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(54) Personal medical apparatus

(57) A personal medication computer includes data entry means, such as a key pad, for entry of data relevant to a user's medical condition and a memory for storing data including pre-programmed prescribed dosage data of a medication for the user. An analysis system provides further data for use in combination with the data stored in memory. A stored programme is used to compute a medication dosage for the user from the stored data and from the data from the analysis system. The computed medication dosage, together with other user information, is shown on a display.

In a preferred example the analysis system comprises a blood glucose meter and the computer calculated insulin dosages for a diabetic user.
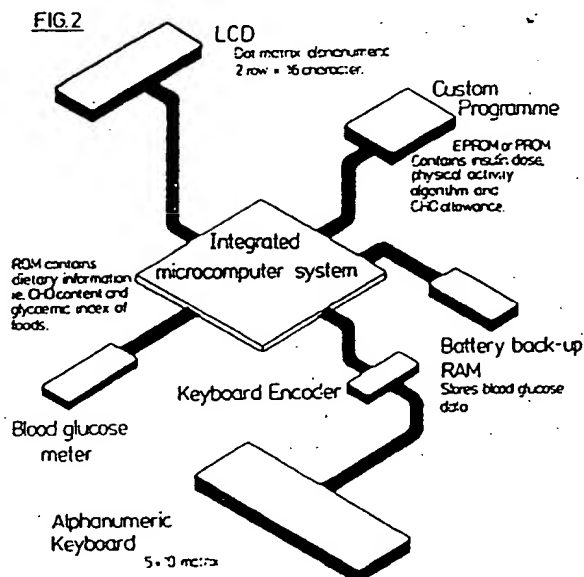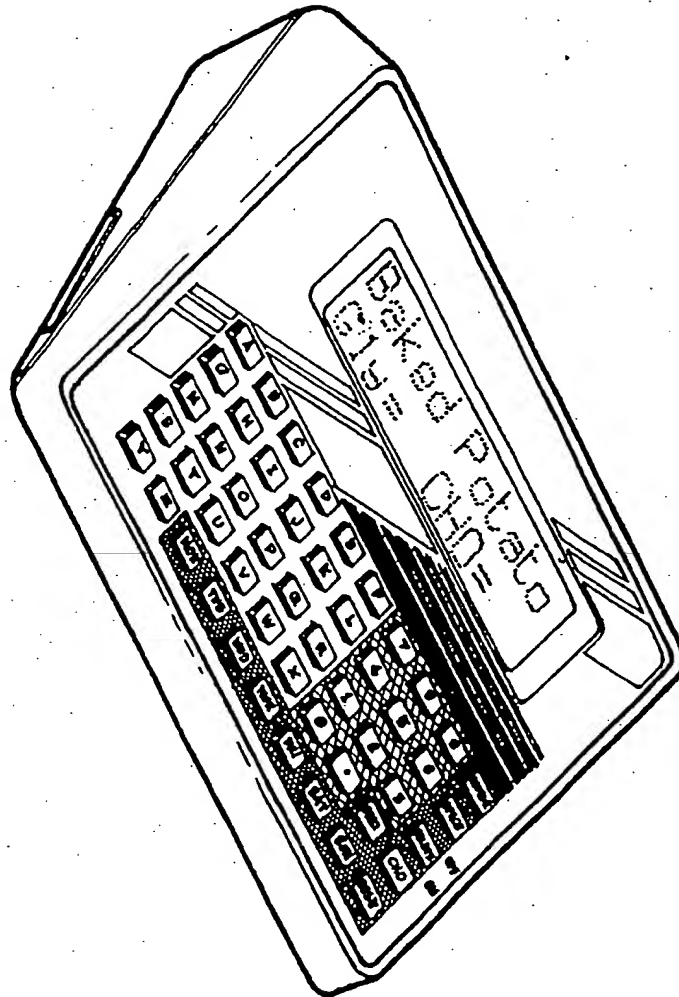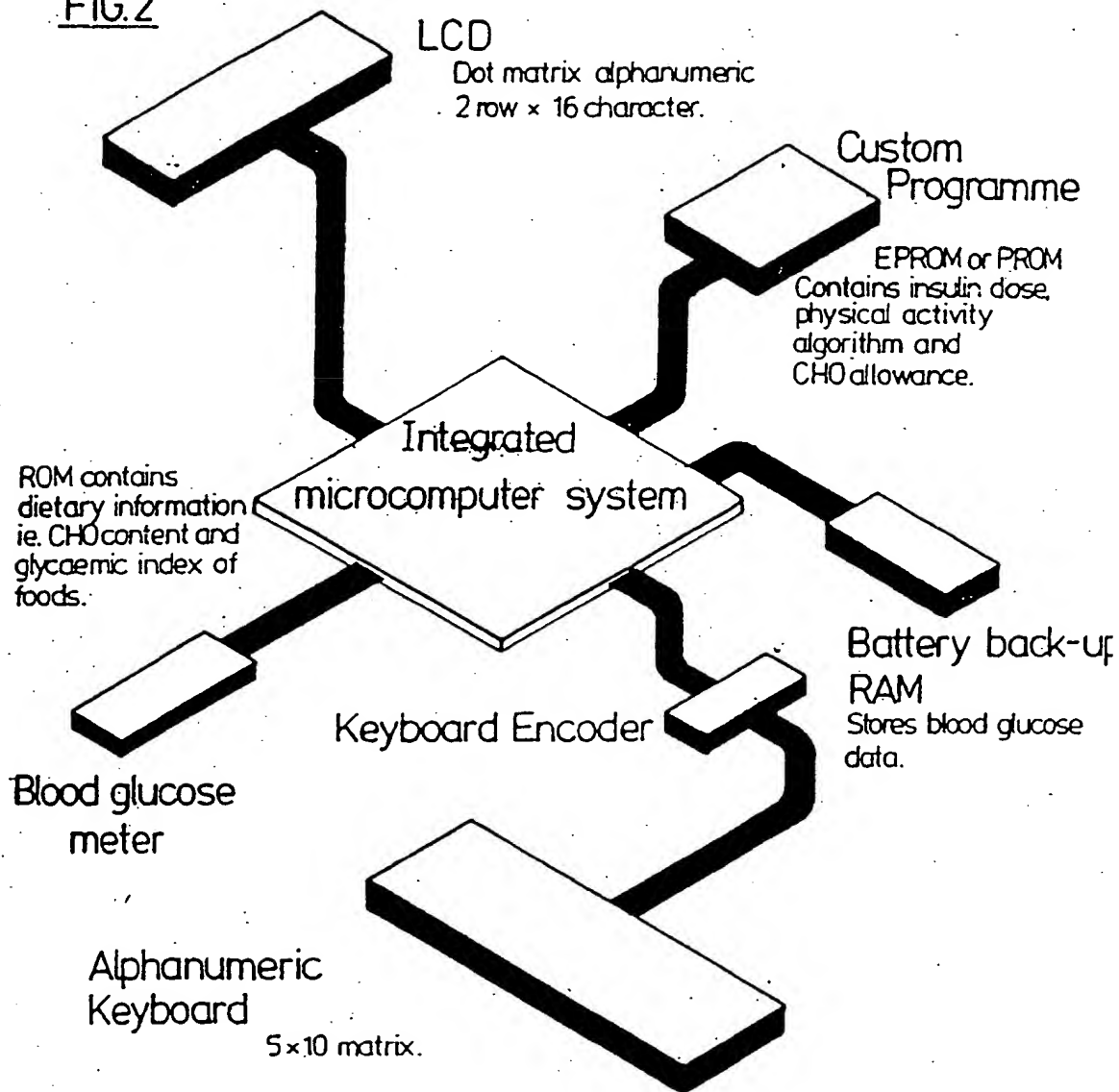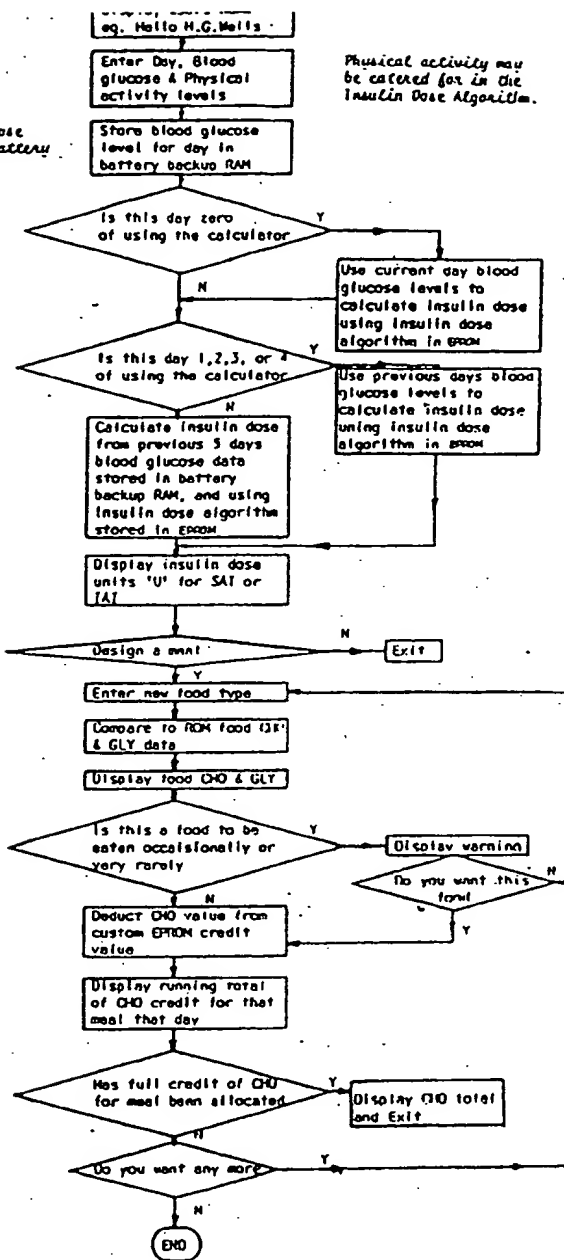

FIG.2

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1982.

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FIG.1

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FIG.2

LCD
Dot matrix alphanumeric
2 row × 16 character.

Custom
Programme

EPROM or PROM
Contains insulin dose,
physical activity
algorithm and
CHO allowance.

Integrated
microcomputer system

ROM contains
dietary information
ie. CHO content and
glycaemic index of
foods.

Battery back-up
RAM
Stores blood glucose
data.

Blood glucose
meter

Keyboard Encoder

Alphanumeric
Keyboard
5×10 matrix.

FIG. 3

eg. Hello H.G.Wells

Enter Day, Blood glucose & Physical activity levels

Physical activity may be catered for in the Insulin Dose Algorithm.

Daily blood glucose data stored in battery backup RAM

Store blood glucose level for day in battery backup RAM

Is this day zero of using the calculator — Y → Use current day blood glucose levels to calculate insulin dose using insulin dose algorithm in EPROM

N

Is this day 1,2,3, or 4 of using the calculator — Y → Use previous days blood glucose levels to calculate insulin dose using insulin dose algorithm in EPROM

N

Calculate insulin dose from previous 5 days blood glucose data stored in battery backup RAM, and using insulin dose algorithm stored in EPROM

Display insulin dose units 'U' for SAI or IAI

Design a meal — N → Exit

Y

Enter new food type

Compare to ROM food CHO & GLY data

Display food CHO & GLY

Is this a food to be eaten occaisionally or very rarely — Y → Display warning → Do you want this food — N / Y

N

Deduct CHO value from custom EPROM credit value

Display running total of CHO credit for that meal that day

Has full credit of CHO for meal been allocated — Y → Display CHO total and Exit

N

Do you want any more — Y

N

END

Acronyms:

CHO = Carbohydrate
GLY = Glycaemic Index
SAI = Short Acting Insulin
IAI = Intermediate Acting Insulin

RAM = Random Access Memory
ROM = Read Only Memory
EPROM = Electrically Programmable Read Only Memory

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This invention relates to the personal medical apparatus. Persons with medical conditions, particularly chronic medical conditions such as diabetes, are faced with the continual problem of organizing their activities and planning ahead so as to follow an individually prescribed course of medication and which may include their diet. At present, many persons with such chronic medical conditions have to rely on a combination of written material, such as diet and medication sheets, and their memory. This can be unreliable and unsatisfactory and leads to a less than optimum control of the medical condition.

According to the present invention there is provided a personal medication computer comprising:

a data entry means, such as a keyboard, for entry at certain times of data relevant to the person's individual medical condition at that time;

a memory storing data relevant to the medical condition including prescribed dosage data of a medication for the person;

a blood glucose meter for the analysis of blood tests which are used in computations and the data stored in a memory (applicable to medical conditions where by blood chemistry is required to be monitored);

a stored program operable to compute a medication dosage for the person on the basis of data entered on said keyboard and data stored in said memory; and

a display to display the computed medication dosage.

person to enter their dietary requirements and preferably also their current expected physical activity level. Daily blood glucose level data are preferably stored in memory for several days. The memory stores insulin dosage data and the stored program is operable to calculate an insulin dosage for the person on the basis of the entered blood glucose level and the stored insulin dosage data. The stored program preferably comprises an insulin dose algorithm involving blood glucose level data over several days and the person's physical activity level.

The stored program preferably also causes the display to display to the person their current individual carbohydrate (CHO) allowance, e.g. for that day.

The stored program is suitably embodied in a PROM and may be adapted and modified on medical advice as the person's diabetic condition alters over a period of time.

The computer may also be provided with a memory storing dietary data relevant to diabetes. The dietary memory may store the CHO content and the glycaemic index of a very large range of foods.

An embodiment of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a personal medication computer according to the invention;

Figure 2 is a schematic block diagram of the major components of the computer; and

Figure 3 is a flow chart describing operation of the computer of Figures 1 and 2.

Diabetes is defined as two types: (1) Insipidus; which is a disorder of the pituitary (a bean sized gland at the base of the brain, controls growth) causing excessive thirst and urination.

(2) Mellitus; a condition in which sugar and starch are not properly absorbed, with thirst, emaciation and excessive urine containing glucose and in extreme cases, acetone as well.

In simple terms, diabetes is a disorder in which the body is unable to control the amount of sugar in the blood, because the mechanism which converts sugar to energy is no longer functioning properly. This leads to an abnormally high level of sugar in the blood, which gives rise to a variety of symptoms initially and, if uncontrolled over several years, may damage tissues of the body. Therefore the treatment of diabetes is designed to reverse any symptoms and prevent any serious problems developing later. Diabetics are unable to produce sufficient quantities or in some cases any insulin. Insulin is produced by the beta cells of the islets of Langerhans within the pancreas (a gland about 150mm x 35mm located behind the lower portion of the stomach) and is responsible for assimilating blood glucose. In a normal person blood sugar rises after a meal and falls again when fasting. Usually, in the fasting state on rising in the morning, the amount of sugar in the blood is about 80mg/100ml, but seldom exceeds 160mg/100ml even after eating a heavy meal containing a lot of sugar. The diabetic usually has a blood sugar level above normal and can easily exceed 200mg/100ml. There is no precise state in which diabetes is present as non-diabetic's blood sugar levels occasionally rise above normal.

lives and planning ahead and following a carefully
structured diet, medication or both. The treatment depends
on the type of diabetes diagnosed, which can range from mild
to severe. The mild type is often called maturity onset,
type two or non-insulin dependent diabetes. The type two
cases occur in middle aged people frequently associated with
obesity. These cases are easily treated by dietary control
to reduce weight and regain normal health. Sometimes diet
alone is not sufficient therefore tablets are prescribed
which stimulate the pancreas to produce more insulin.
Severe diabetes often termed type one or juvenile onset
diabetes and can occur at any age, but is typified by that
occurring in children and young adults. The onset of
diabetes in these cases is generally more sudden and the
symptoms more severe. Treatment is also more complex as it
involves diet and insulin injections. Checks are performed
by the patient in the form of urine and blood tests. These
give a good indication of the control a patient has and how
the diet and medication are working. It is the type one
insulin dependent diabetes mellitus (IDDM) where the
invention has its best defined niche.

The invention can be of greatest benefit to people with
IDDM, and can give information on a prescribed treatment
based on blood tests presently carried out by diabetics as a
part of their daily routine treatment. Blood glucose meters
are used for accurate readings on blood glucose tests. One
of the many existing or newly developed blood glucose meters
can be a part of the invention with the blood glucose data
being fed directly to the microcomputer system. From this
data is calculated the insulin dose to be injected and the
quantity displayed to the user. The user is then offered an
option to calculate dietary values of foods.

The invention is intended to give greater precision, control and simplify the process in which diabetics have to adhere to in order to control their condition and maintain good health. At present, diet sheets, a prescribed medication and diet are used in various combinations to treat diabetes depending on the type. This data has to be remembered or referred to.

The invention can hold all this information thus avoiding having to resort to memory. As each persons's requirements are totally individual and subject to change due to time, accidents, stress, illness, life style etc. the invention contains a custom program which houses all personal data. The custom program can easily and quickly be updated. To every patient one thing will be common, that is the CHO values of foods, normally expressed in terms of "exchanges" where one exchange = a quantity of food containing 10g of CHO. This information is stored in a ROM.

The invention is used by first conducting the blood glucose test, this information is relayed to the microcomputer system which processes it and displays on the display the quantity of insulin to be injected. The user is then presented with an option to compile a meal or "design a meal". A CHO value is displayed taken from the custom program which is their CHO allowance. The CHO allowance is treated as a credit value to be consumed evenly over the day in the form of set meals and snacks. On entering a food value the food CHO value is taken from the allowance and a running total remaining is displayed. Foods entered that should not be eaten or eaten very occasionally prompts a warning to be displayed. It will be appreciated that use of the invention enables a diabetic person to maintain better control of their condition, they do not have to remember food values, they can easily determine their optimum diet and medication and they can easily determine the glycaemic index and CHO values of a very wide range of foods.

changing the batteries and updating the custom program.   As
the invention is designed for ease of portability, its size
is small.   Therefore some sacrifice is made to the ideal
sized alphanumeric keyboard.   Even so a miniature keyboard
for this application is not required for high speed data
input. A small amount · of information has to be keyed in,
akin to that of an ordinary pocket calculator.

   The   invention preferably looks neat,   compact   and
conservatively stylish.   Consideration must be made for
appearance as the largest age group to use this device are
children and young adults.

Just over 2% of the U.K. population (600,000) are diagnosed
as being diabetic (of this approximately 30,000 are under
the age of sixteen) with an estimated 600,000 undiagnosed.
Nearly 30,000 diabetes cases are diagnosed in the U.K. each
year.   There are over 30 million diagnosed diabetics in the
world with another 30 million undiagnosed. Over 30% of
diabetics are insulin dependent and affects a population age
spread of 10 years of age upwards. This in theory gives a
maximum possible market potential of 200,000 in the U.K. and
something in the order of 10 million world wide.   An
additional 10,000 insulin dependent diabetics are diagnosed
in the U.K. alone each year. The invention can be adapted
for other medical conditions or illnesses requiring dietary
and or medication management and control. Just diet control
would be another application.
Insulin dosage adjustments using computer algorithms: a
comparative study was published in the Medical & Biological
Engineering & Computing magazine, November 1986. Below are
the algorithms that produced superior results in respect to
the speed of improving diabetes control and the avoidance of
undesirable hypoglycaemia. The algorithms were tested based
on the following assumptions. The morning short-acting
insulin (SAIB) had major action between breakfast and lunch.

Also, the morning intermediate-acting (NPH or Lente) insulin (IAIB) had major action between lunch and dinner, and its effect was reflected in the blood glucose concentration before dinner. The evening short-acting insulin (SAID) had major action between dinner and bedtime, and its effect was reflected in the blood in the blood glucose level at bedtime. Finally, the evening intermediate-acting insulin (IAID) had major action overnight, and its effect was reflected in the blood glucose test results on arising the next morning.

Accordingly, the specific insulin dose adjusting algorithms implemented were as follows. All doses were in units (U) and the blood glucose concentrations were in dl^{-1}.

$$IAID_0 = IAID_{-1} + \sum_0^{-5}(BGB - 110)i / \sum_0^{-5} S_1 i$$

<p align="right">1</p>

$$= IAID_0[9(BGB_0 < 50) + 10(BGB_0 \geqslant 50)]/10$$

Where $IAID_0$ represented the intermediate-acting insulin dose at dinner on day 0, the current day. The '=' sign should be read as 'is replaced by' and the inequalities assumed binary values of 1 (true) or 0 (false). $IAID_{-1}$ represented the intermediate-acting insulin dose taken at dinner the previous day. BGB represented the breakfast blood glucose level in the summation, which was over the current and previous days with i = 0 to -5. $S_1 i$ were sensitivity factors which weighted the summation. BGB_0 represented the prebreakfast plasma glucose level on day 0.

$$IAIB_0 = IAIB_{-1} + \sum_{-1}^{-5}(BGD - 110)i / \sum_{-1}^{-5}S_2 i$$

2

$$= IAIB_0 \, [9(BGD_0 < 50) + 10(BGD_0 \geqslant 50)]/10$$

where $IAIB_0$ represented the intermediate-acting insulin dose at breakfast on day 0 and $IAIB_{-1}$ that of the previous day. BGB was the predinner plasma glucose level and the summation was over the five previous days with i = -1 to -5 and $S_2 i$ were other sensitivity factors. BGD_0 was the predinner plasma glucose concentration of the current day.

$$SAIB_0 = SAIB_{-1} + \sum_{-1}^{-5}(BGL - BGB)i/\sum_{-1}^{-5}S_3i + (BGB - 110)_0/S_4i$$

3

$$= SAIB_0 [9(BGL_0 < 50) + 10(BGL_0 \geqslant 50)]/10$$

where $SAIB_0$ represented the short-acting insulin dose at breakfast on day 0 and $SAIB_{-1}$ the corresponding dose the previous day. BGL and BGB were, respectively, the prelunch and prebreakfast plasma glucose levels on the current and each previous day. S_3i and S_4i were sensitivity factors.

$$SAID_0 = SAID_{-1} + \sum_{-1}^{-5}(BGS - BGD)i/\sum_{-1}^{-5}S_5i + (BGD - 110)_0/S_6i$$

4

$$= SAID_0 [9(BGS_0 < 50) + 10(BGS_0 \geqslant 50)]/10$$

where $SAID_0$ was the short-acting insulin dose at dinner on day 0 and $SAID_{-1}$ the corresponding dose of the previous day. BGS and BGD were, respectively, the presnack and predinner plasma glucose levels of the current and each previous day. S_5i and S_6i were sensitivity factors.

CLAIMS

1.   A personal medication computer comprising data entry
means for entry of data relevant to a user's medical
condition; a memory for storing data including
pre-programmed prescribed dosage data of a medication for
the person; an analysis system for the analysis of data
for use in computations in combination with the data
stored in memory; a stored program operable to compute a
medication dosage for the person on the basis of data
entered on said data entry means, data from said analysis
system and data stored in said memory; and a display to
display the computed medication dosage and user
information.

2.   A personal medication computer as claimed in claim
1, wherein the data entry means comprise a key pad.

3.   A personal medication computer as claimed in claim 1
or claim 2, wherein the memory comprises a PROM for
storing pre-programmed data relevant to the medical
condition including prescribed dosage data of a
medication for the user and a RAM for storing data
entered via the data entry means.

4.   A personal medication computer as claimed in claim
3, wherein the analysis system comprises a blood glucose
meter connected to a data input of the computer to
provide data for storage in memory and for use, in
combination with the pre-programmed data, in calculation
of a medication dosage.

5.   A personal medication computer as claimed in claim
4, wherein the RAM has a battery back-up to enable
non-volatile storage of data from the blood glucose meter
and the stored programme is operable to calculate a
medication dosage from a current meter reading and a

pre-determined number of previous meter readings stored
in the RAM.

6. A personal medication computer substantially as
described herein with reference to Figures 1-3 of the
5 accompanying drawings.

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